You must also, as soon as possible, inform the DER and collection site supervisor that a collection took place under direct observation and the reason for doing so.

(3) In a case where the employee refuses to provide a specimen under direct observation (see §40.191(a)(4)), you must discard any specimen the employee provided previously during the collection procedure. Then you must notify the DER as soon as practicable.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41950, Aug. 9, 2001]

#### § 40.67 When and how is a directly observed collection conducted?

- (a) As an employer, you must direct an immediate collection under direct observation with no advance notice to the employee, if:
- (1) The laboratory reported to the MRO that a specimen is invalid, and the MRO reported to you that there was not an adequate medical explanation for the result;
- (2) The MRO reported to you that the original positive, adulterated, or substituted result had to be cancelled because the test of the split specimen could not be performed; or
- (3) The laboratory reported to the MRO that the specimen was negative-dilute with a creatinine concentration greater than or equal to 2 mg/dL but less than or equal to 5 mg/dL, and the MRO reported the specimen to you as negative-dilute and that a second collection must take place under direct observation (see §40.197(b)(1)).
- (b) As an employer, you may direct a collection under direct observation of an employee if the drug test is a return-to-duty test or a follow-up test.
- (c) As a collector, you must immediately conduct a collection under direct observation if:
- (1) You are directed by the DER to do so (see paragraphs (a) and (b) of this section); or
- (2) You observed materials brought to the collection site or the employee's conduct clearly indicates an attempt to tamper with a specimen (see §§ 40.61(f)(5)(i) and 40.63(e)); or
- (3) The temperature on the original specimen was out of range (see §40.65(b)(5)); or (4) The original speci-

men appeared to have been tampered with (see \$40.65(c)(1)).

- (d)(1) As the employer, you must explain to the employee the reason for a directly observed collection under paragraph (a) or (b) of this section.
- (2) As the collector, you must explain to the employee the reason, if known, under this part for a directly observed collection under paragraphs (c)(1) through (3) of this section.
- (e) As the collector, you must complete a new CCF for the directly observed collection.
- (1) You must mark the "reason for test" block (Step 1) the same as for the first collection.
- (2) You must check the "Observed, (Enter Remark)" box and enter the reason (see §40.67(b)) in the "Remarks" line (Step 2).
- (f) In a case where two sets of specimens are being sent to the laboratory because of suspected tampering with the specimen at the collection site, enter on the "Remarks" line of the CCF (Step 2) for each specimen a notation to this effect (e.g., collection 1 of 2, or 2 of 2) and the specimen ID number of the other specimen.
- (g) As the collector, you must ensure that the observer is the same gender as the employee. You must never permit an opposite gender person to act as the observer. The observer can be a different person from the collector and need not be a qualified collector.
- (h) As the collector, if someone else is to observe the collection (e.g., in order to ensure a same gender observer), you must verbally instruct that person to follow procedures at paragraphs (i) and (j) of this section. If you, the collector, are the observer, you too must follow these procedures.
- (i) As the observer, you must request the employee to raise his or her shirt, blouse, or dress/skirt, as appropriate, above the waist; and lower clothing and underpants to show you, by turning around, that they do not have a prosthetic device. After you have determined that the employee does not have such a device, you may permit the employee to return clothing to its proper position for observed urination.
- (j) As the observer, you must watch the employee urinate into the collection container. Specifically, you are to

#### § 40.69

watch the urine go from the employee's body into the collection container.

- (k) As the observer but not the collector, you must not take the collection container from the employee, but you must observe the specimen as the employee takes it to the collector.
- (I) As the collector, when someone else has acted as the observer, you must include the observer's name in the "Remarks" line of the CCF (Step 2)
- (m) As the employee, if you decline to allow a directly observed collection required or permitted under this section to occur, this is a refusal to test.
- (n) As the collector, when you learn that a directly observed collection should have been collected but was not, you must inform the employer that it must direct the employee to have an immediate recollection under direct observation.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41950, Aug. 9, 2001; 68 FR 31626, May 28, 2003; 69 FR 64867, Nov. 9, 2004; 73 FR 35970, June 25, 2008]

EFFECTIVE DATE NOTE: At 73 FR 35970, June 25, 2008, §40.67(b) was revised, effective August 25, 2008. At 73 FR 50223, August 26, 2008, the effective date was delayed until November 1, 2008. For the convenience of the user, the revised text is set forth as follows:

# $\S$ 40.67 When and how is a directly observed collection conducted?

\* \* \* \* \*

(b) As an employer, you must direct a collection under direct observation of an employee if the drug test is a return-to-duty test or a follow-up test.

\* \* \* \* \*

# § 40.69 How is a monitored collection conducted?

- (a) As the collector, you must secure the room being used for the monitored collection so that no one except the employee and the monitor can enter it until after the collection has been completed.
- (b) As the collector, you must ensure that the monitor is the same gender as the employee, unless the monitor is a medical professional (e.g., nurse, doctor, physician's assistant, technologist, or technician licensed or certified to practice in the jurisdiction in which

the collection takes place). The monitor can be a different person from the collector and need not be a qualified collector.

- (c) As the collector, if someone else is to monitor the collection (e.g., in order to ensure a same-gender monitor), you must verbally instruct that person to follow the procedures of paragraphs (d) and (e) of this section. If you, the collector, are the monitor, you must follow these procedures.
- (d) As the monitor, you must not watch the employee urinate into the collection container. If you hear sounds or make other observations indicating an attempt to tamper with a specimen, there must be an additional collection under direct observation (see §§ 40.63(e), 40.65(c), and 40.67(b)).
- (e) As the monitor, you must ensure that the employee takes the collection container directly to the collector as soon as the employee has exited the enclosure.
- (f) As the collector, when someone else has acted as the monitor, you must note that person's name in the "Remarks" line of the CCF (Step 2).
- (g) As the employee being tested, if you decline to permit a collection authorized under this section to be monitored, it is a refusal to test.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41951, Aug. 9, 2001]

### § 40.71 How does the collector prepare the specimens?

- (a) All collections under DOT agency drug testing regulations must be split specimen collections.
- (b) As the collector, you must take the following steps, in order, after the employee brings the urine specimen to you. You must take these steps in the presence of the employee.
- (1) Check the box on the CCF (Step 2) indicating that this was a split specimen collection.
- (2) You, not the employee, must first pour at least 30 mL of urine from the collection container into one specimen bottle, to be used for the primary specimen.
- (3) You, not the employee, must then pour at least 15 mL of urine from the collection container into the second specimen bottle to be used for the split specimen.